

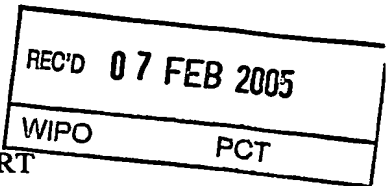
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference ORM-231WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/30917	International filing date (day/month/year) 26 September 2003 (26.09.2003)	Priority date (day/month/year) 26 September 2002 (26.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61C 3/00 and US Cl.: 433/24		
Applicant ORMCO CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 20 April 2004 (20.04.2004)	Date of completion of this report 29 November 2004 (29.11.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>A. Hurley for</i> Cary E. O'Connor Telephone No. 703-308-0858

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/30917

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-20 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages NONE _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages 21-26 _____, filed with the letter of 12 October 2004 (12.10.2004)
- ☒ the drawings:
pages 1-45 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☒ the claims, Nos. 45-48
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/30917

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 11-15

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 11-15

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/30917**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-10 and 16-44</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-10 and 16-44</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-10 and 16-44</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/30917

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V. 2. Citations and Explanations:

Claims 1-8 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of representing a three dimensional tooth object comprising, inter alia, selecting groove and cusp points from the three dimensional displayed object, defining from the selected groove and cusp points line segments representative of the orientation of the tooth object using the parameters set forth in the claims.

Claims 9 and 10 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of forming a digital image of a tooth comprising forming a 3-D tooth object of the crown of a tooth by scanning, and adding tooth root data to the tooth object from a separate file or object that contains three dimensional data of individual tooth roots.

Claim 16 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of calculating an orthodontic setup of a patient's teeth including calculating the rotation of teeth wherein the rotation of a tooth is defined as the angle of a tooth measured relative to the zero angle of the tooth relative to the tangent of the archform.

Claims 17-19 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of calculating an orthodontic setup including calculating a symmetrical arch by superimposing images of contralateral teeth in MDL.Pt cross-sectional views with their PAW.Pts coincident and rotating images of the teeth about the PAW.Pt until predetermined occlusal angles of the teeth are at an average value.

Claims 20 and 21 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of calculating an orthodontic setup including comprising, inter alia, calculating a symmetrical arch comprising fixing FIE.Pts of the lower incisors to align the lower incisal edges to a best fit buccal cusp curve.

Claims 22, 23, 38, 41 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of determining a dental arch comprising displaying the dental anatomy, and representing a dental arch on the display with a bezier curve having anterior bezier and posterior bezier handles.

Claims 24 and 25 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of calculating an orthodontic setup comprising providing an operator with an interface on which to select teeth for extraction and providing a computer programmed with a plurality of setup calculation routines, each responsive to a different tooth extraction selection.

Claims 26-28 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of providing a custom orthodontic appliance comprising, inter alia, storing in a database, information identifying practitioners and

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/30917

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

information relating to treatment plan options preferred by the practitioners, receiving information from a practitioner, determining parameters for the configuration of the appliance based at least in part on the preferred stored options.

Claims 29-31 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of determining an arrangement of teeth to achieve by orthodontic treatment comprising scanning the shapes of the teeth, deriving an arrangement of the teeth from the scanned data, and taking steps to reduce the amount of data prior to deriving the arrangement.

Claims 32-37 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method comprising scanning the teeth, processing the scanned data automatically using feature recognition software to isolate tooth objects, then displaying the automatically processed generated data to an operator to resolve ambiguities or errors or to verify the isolated objects.

Claims 39 and 40 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of determining an orthodontic setup comprising producing tooth data, and defining a mid-developmental lobe plane for each tooth.

Claims 42-44 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of representing a three dimensional tooth object comprising, inter alia, arranging tooth objects at angles of the teeth for each tooth in their own XYZ coordinate system, Z being perpendicular to an occlusal plane, X being a mesial distal axis of the tooth, and wherein tooth torque angle is set in a plane perpendicular to the X axis and tip angle is set as the angle of the plane relative to the X axis.

Claims:

1. A method of representing a three dimensional tooth object for use in determine an orthodontic setup of the teeth, comprising:
- 5 displaying data of a three-dimensional object for lower molars;
- selecting groove and cusp points from the displayed object by selecting a distal-lingual groove point (DLG.Pt), a distal-lingual cusp point (DLC.Pt), a mesial-lingual cusp point (MLC.Pt), a facial cusp point (FC.Pt), and a mesial-facial cusp point (MFC.Pt) from the displayed object; and
- 10 defining from the selected groove and cusp points line segments representative of the orientation of the tooth object by defining from points DLC.Pt and MLC.Pt a labial cusp line segment (LC.Li), from points FC.Pt and MFC.Pt a facial cusp line segment (FC.Li), from points DLG.Pt and MFC.Pt a line segment Stolar.Li.
2. The method of claim 1 further comprising calculating the occlusion of upper molars based on the defined line segments.
3. The method of claim 1 further comprising:
- 15 defining an occlusal table line segment (OT.Li) perpendicular to LC.Li, coincident with the buccal groove, and connecting FC.Li to LC.Li, representing a mid-developmental lobe plane (MDL.PI).
4. The method of claim 3 further comprising:
- defining the initial mesial-distal positioning of an appliance on the tooth in relation to the mid-developmental lobe plane (MDL.PI).
- 20 5. The method of claim 1 wherein:
- the selecting includes:
- selecting a mesial-lingual cusp point (MLC.Pt), a distal-lingual cusp point (DLC.Pt), a mesial facial cusp point (MFC.Pt), and a distal-facial cusp point (DFC.Pt), and
- 25 selecting mesial and distal marginal ridges as points MMR.Pt and DMR.Pt, respectively; and
- the defining includes:
- defining from points MLC.Pt and DLC.Pt a labial cusp line segment (LC.Li), from points MFC.Pt and DFC.Pt a facial cusp line segment (FC.Li),
- defining a marginal ridge line segment (MR.Li) as that through points MMR.Pt and DMR.Pt, and
- defining from points MMR.Pt and DLC.Pt a line segment Stolar.Li.
- 30 6. The method of claim 5 further comprising:
- calculating the occlusion with lower molars using the line Stolar Li.
7. The method of claim 5 further comprising:
- selecting points MFC.Pt and MLC.Pt to define mesial cusp line segment (MC.Li);

- 22 -

defining occlusal table line segment (OT.Li) to be parallel to line MC.Li, coincident with the buccal groove, and connecting FC.Li to LC.Li; and
defining with line OT.Li the mid-developmental lobe plane (MDL.PI).

5 8. The method of claim 7 further comprising defining the initial mesial-distal positioning of an appliance on the tooth in relation to the mid-developmental lobe plane (MDL.PI).

9. A method of forming a digital image of a tooth comprising:
forming a 3-D tooth object of the crown of a tooth by scanning the tooth or a model thereof; and
adding tooth root data to the tooth object from a separate file or object that contains three dimensional data of one or more individual tooth roots.

10 10. The method of claim 9 wherein the tooth root data is produced by scans of the patient's individual anatomy.

11. The method of claim 9 wherein the teeth root data is retrieved from library files or records that contain three-dimensional shape data of anatomically representative tooth roots.

12. The method of any of claims 9-11 further comprising:
15 modifying the tooth root data from information from the tooth crown scans.

13. The method of any of claims 9-12 further comprising:
joining the crown and root data to form complete tooth objects by aligning the crown long axis and the root long axis from the respective data.

14. The method of claim 13 further comprising:
20 setting the alignment to a selected or calculated relative torque angle.

15. The method of any of claims 9-14 further comprising:
using root image data that represent the tooth root at less than full scale relative to that of the crown;
incrementally increasing in size the tooth root data until any part of the root touches a corresponding point in the crown;
25 when this contact occurs, fixing the expansion of the root at the contact point and proportionately scaling the rate of expansion from the contact point until the root has been expanded and the rims of the crown and root fully coincide.

16. The method of calculating an orthodontic setup of a patient's teeth including calculating the rotation of individual teeth to produce an occlusion wherein the rotation of a tooth is defined as the angle of a tooth measured relative to the zero angle of the tooth relative to the tangent of the archform in which
30

the teeth are arranged, the angle of the tooth relative to said zero angle in the calculated setup being varied to satisfy an occlusion condition.

5 17. The method of calculating an orthodontic setup of a patient's teeth including calculating a symmetrical arch by superimposing images of contralateral teeth in MDL.PI cross-sectional views with their PAW.Pts coincident and rotating images of the teeth about the PAW.Pt until predetermined occlusal angles of the teeth are at an average value.

18. The method of claim 17 further comprising extruding or intruding the teeth in a direction normal to the occlusal plane until the buccal cusp points of the teeth are coincident with the occlusal plane.

10 19. The method of claim 18 further comprising defining the horizontal distance from the buccal cusp point (BC.Pt) to PAW.Pt as the prominence line (PR.Li), and establishing said line to an average value by adjusting the BC.Pts.

15 20. The method of calculating an orthodontic setup of a patient's teeth including calculating a symmetrical arch comprising fixing FIE.Pts of the lower incisors to align the lower incisal edges to a best fit buccal cusp curve to enable placement of upper incisors, setting the BC.Pt of teeth lower incisors to an average value from FIE.Pt along MDL.PI, finding the intersection of MDL.PI and midline from the mandibular trough for lower central incisors and calculating the line segment distance from BC.Pt along MDL.PI to intersection for both teeth.

20 21. The method of claim 20 further comprising calculating from the intersections, a respective distance equal to said line segments facially along midline, averaging points at the measured distances on midline to define thereby the origin of an anterior bezier handle, and defining the mesial facial cusps of lower molars as posterior bezier handles.

25 22. A method of determining a dental arch for arrangement of a patient's teeth comprising: displaying dental anatomy of a patient on a display for adjustment by an operator; and representing a dental arch on the display with a bezier curve having anterior bezier and posterior bezier handles by which the operator can alter the shape of the arch on the display.

23. The method of claim 21 or claim 22 further comprising moving the handles by an operator to adjust the curve and setting the curve as a default best fit buccal cusp curve.

30 24. A method of calculating an orthodontic setup of teeth comprising: providing an operator with an interface on which to select teeth for extraction; providing a computer in communication with the interface and programmed with a plurality of setup calculation routines, each responsive to a different tooth extraction selection on the interface; and

calculating the setup eliminating therefrom the teeth selected by an operator on the interface for extraction with the assistance of the computer in accordance with the calculation routine responsive to the tooth extraction selection made by the operator on the interface.

25. The method of claim 24 further comprising:
 5 providing an operator with the option of selecting teeth on different arches or different sides of an arch differently;
 calculating the setup separately for each arch or side of an arch to provide for asymmetric extraction.

26. A method of providing a custom orthodontic appliance for treatment of a patient, the method
 10 comprising:
 maintaining a database, accessible by a computer, and containing data related to each of a plurality of orthodontic practitioners;
 storing in the database, information identifying the practitioners and information relating to treatment plan options preferred by the respective practitioners;
 15 receiving information from an orthodontic practitioner of the plurality for providing a custom orthodontic appliance for a patient;
 in response to the information from the practitioner, determining parameters for the configuration of a custom orthodontic appliance for the patient based at least in part on the stored options preferred by the orthodontic practitioner; and
 20 providing an orthodontic appliance design for the patient having a configuration that includes the determined parameters.

27. The method of claim 26 further comprising:
 receiving information from the orthodontic practitioner of a treatment plan option for treatment of the patient; and
 25 determining at least one of the parameters based at least in part on the information of the treatment plan option received from the orthodontic practitioner.

28. The method of claim 26 further comprising:
 receiving information from the orthodontic practitioner of a treatment plan option for treatment of the patient; and
 30 determining parameters addressed by the information of the treatment plan option received from the orthodontic practitioner in accordance with that information and determining parameters not so addressed in accordance with information stored in the database.

29. A method of determining an arrangement of the teeth of a patient to achieve by orthodontic treatment, comprising:

scanning shapes of the patient's teeth to generate one or more data files thereof;
deriving an arrangement of the patient's teeth from the data with the aid of a computer;
taking steps to reduce the amount of the data prior to deriving the arrangement.

30. The method of claim 29 wherein:

5 said steps include pruning the files to minimize unnecessary information the deriving of the arrangement.

31. The method of claim 29 wherein:

the scanning includes scanning a model or impression of the teeth;
said steps include manicuring or trimming the model or impression before scanning.

10 32. A method of determining an arrangement of the teeth of a patient comprising:
scanning shapes of a plurality of teeth of a patient and generating data of the plurality; then
processing the generated data automatically using feature recognition software to isolate tooth objects;
then
displaying the automatically processed generated data to an operator to resolve ambiguities or errors
15 or to verify the isolated objects.

33. The method of claim 32 further comprising:

manipulating the displayed data to repair the isolated objects to remove artifacts.

34. The method of claim 33 wherein:

the manipulating includes modifying tooth crown shapes in the data to eliminate interferences.

20 **35.** The method of claim 33 wherein:
the manipulating is performed on a computer display by an operator with the aid of software tools.

36. The method of claim 33 wherein:

the manipulating includes selecting, then elevating, lowering or smoothing areas that could cause poor jig adaptation.

25 37. The method of claim 32 further comprising:
thinning data of unnecessary resolution.

38. A method of determining an arch shaped arrangement for an orthodontic setup of the teeth, comprising:

generating on a computer a mandibular model of the patient's teeth that includes gingival or jaw shape data;

generating a section through the model through the gingiva or jaw;
selecting points defining facial and lingual boundaries and defining thereby a mandibular trough of
the patient;
displaying the mandibular trough on a computer display; and
5 calculating a smooth symmetrical bezier curve through the trough between corresponding labial and
lingual points, the curve having handles at the midline and at the distal ends thereof to allow an operator
to modify the shape of the bezier curve.

39. A method of determining an orthodontic setup of the teeth, comprising:
producing data representing each of a plurality of a patient's teeth;
10 defining for each tooth a mid-developmental lobe plane.

40. The method of claim 39 wherein the defining includes:
defining for the tooth, a mid-developmental lobe axis (MDL.Ax) by selection of its extents incisally
(IMDL.Pt) and gingivally (GMDL.Pt);
defining through MDL.Ax and perpendicular to a mesial-distal axis of the tooth, a mid developmental
15 lobe plane.

41. The method of claim 38 further comprising:
define a crown long axis for the tooth in the mid developmental lobe plane.

42. A method of representing a three dimensional tooth object for use in determine an orthodontic
setup of the teeth, comprising:
20 arranging tooth objects at angles of the teeth for each tooth in their own XYZ coordinate systems, in
which Z is perpendicular to an occlusal plane and X is a mesial-distal axis for the tooth;
wherein tooth torque angle is set in a plane perpendicular to the X axis, tip angle is set as the angle
of the plane relative to the X axis.

43. The method of claim 42 further comprising:
25 defining a set-up by arranging the coordinate systems of the teeth.

44. The method of claim 42 further comprising:
defining a set-up by arranging the coordinate systems of the teeth with the coordinate systems
rotated relative to each other to a value determinative of tooth rotation.